

REMARKS

The present application relates to inbred maize line PH951. Claims 1-36 are pending in the present application. Claims 7, 9, 16 and 25-28 have been amended. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

Applicant acknowledges that because this application is eligible for continued examination under 37 C.F.R. § 1.114 and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant further acknowledges that Applicant's submission filed on October 13, 2005 has been entered.

Claim Objections

The Examiner objects to claim 16 and suggests "wherein seed is allowed to form" be replaced with --and harvesting seed-- for clarification. Applicant has amended the claim as suggested by the Examiner, thus alleviating this objection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 13-14, 25-30 and 34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states claim 13 is indefinite "for omitting essential steps." See Office Action, pp. 2-3.

Applicant traverses this rejection. Applicant has included "repeating steps (c) and (d) to produce backcross progeny plants that comprise the desired trait and comprise at least 95% of the alleles of inbred line PH951 at the SSR loci listed in Table 4" in claim 13. Applicant further asserts the use of molecular marker profiles by those of ordinary skill in the art in backcrossing is also clearly supported by the scientific literature. For example, see Ragot, M. *et al.* (1995) Marker-assisted backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moléculaires (Les Colloques)*, Vol. 72, pp. 45-56 (attached as Appendix 1), and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data,

pp. 41-43 (attached as Appendix 2). Specifically, Ragot *et al.* states in the first sentence of the summary "[t]hat molecular markers allow fast recovery of recurrent parent genotype in backcross programs is undisputed," and, in the first sentence of the introduction, "[b]ackcrossing has been a common breeding practice for as long as elite germplasm has been available." Therefore, Applicant has claimed in the manner used by those of ordinary skill in the art to characterize backcross conversions.

Claim 14 is rejected as rejected as indefinite as depending from rejected claim 13.

Applicant traverses this rejection for the reasons asserted *supra*. Claim 14 is definite and does include the essential method steps of claim 13.

Regarding claims 25 and 27-30, the Examiner states that the claims "do not incorporate all elements of the parent claim 15," specifically that the "plant of parent claim 15 does not contain a single locus conversion, a dominant or recessive allele/transgene." *See* Office Action, p. 3.

Applicant respectfully traverses. Claim 15 specifically claims a maize plant having all the physiological and morphological characteristics of inbred line PH951. Claim 15 encompasses maize plants having the characteristics of inbred line PH951. Claims 25 and 27-30 claim the maize plant of claim 15 with these additional limitations, which are not necessarily present in the maize plant of claim 15. The presence of these additional limitations does not mean that claims 25 and 27-30 do not possess all limitations of claim 15; these claims still require a maize plant having the physiological and morphological characteristics of inbred line PH951. Because claims 25 and 27-30 do incorporate all elements of claim 15, they are in accordance with the requirements of § 112, second paragraph.

The Examiner further states that claims 28-30 are indefinite in the "recitation of 'male sterility' because the plant of parent claim 15, PH951, is male fertile." *See* Office Action, p. 3.

Applicant respectfully traverses. It would be understood by one of ordinary skill in the art that the deposited line can be manipulated and made male sterile by methods such as backcrossing, as described in the specification. *See, e.g.*, specification, pp. 2-4. "It should be understood that the inbred can, through routine manipulation by detasseling, cytoplasmic genes, nuclear genes, or other factors, be produced in a male-sterile form." *See* specification, p. 36, ll. 20-22. One of skill in the art also understands that transgenes can be incorporated into the inbred line in a similar manner. *See* specification, pp. 38-48. Male sterile conversions have been made

to inbred lines since the 1950's, and transgenic conversions have been made to inbred lines since the early 1990's. Both are routinely made, and the language and meaning of these claims are well understood by plant breeders. The primary purpose of the requirement of definiteness of claim language is to "ensure that the scope of the claim is clear so the public is informed of the boundaries." MPEP § 2173. That objective has been satisfied by claims 28-30.

Claim 34 is rejected as indefinite in the recitation of "using" without any active method steps. *See Office Action*, p. 3.

Applicant traverses this rejection. The specification states "[p]lant breeding techniques known in the art and *used* in a maize plant breeding program include, but are not limited to, recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, making double haploids, and transformation. Often a combination of these techniques are used." Specification, p. 4, ll. 8-13 (emphasis added). Therefore, Applicant asserts that one of skill in the art would know the meaning of the term "using" in claim 34.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-12 remain rejected and claims 17-21, 23, 25-28, 31-32 and 34-36 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner states the rejection is repeated for claims 1-12 and applied to new claims 17-21, 23, 25-28, 31-32 and 34-36 for the reasons of record set forth in the Office Action of July 13, 2005. *See Office Action*, p. 3.

Applicant respectfully traverses this rejection. Applicant reiterates that the written description requirement of § 112, first paragraph has been fulfilled by depositing seeds of PH951 in a public depository and by referencing the deposit in the specification. *See* specification, p. 65, ll. 2-28; *see also Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002) (stating that the written description requirement of § 112, ¶ 1 may be

fulfilled by depositing material in a public depository, where the deposited material is not accessible in writing, and where reference to the deposit is made in the specification). This deposit not only describes inbred maize line PH951 but also the hybrid maize plants, plant parts, and seeds grown of claims 1-12, 17-21, 23, 25-28, 31-32 and 34-36. In a prior case before the Board of Patent Appeals and Interferences, the Board determined that where claims to an inbred maize plant satisfied the written description requirement, claims to the F1 hybrid seed and plants with the inbred maize plant as a parent also satisfied the written description requirement. *See Ex parte Carlson* (B.P.A.I. 2005). The Board therein stated:

All that is required by the claims is that the hybrid has one parent that is a plant of corn variety [inbred]. Since the examiner has indicated that the seed and the plant of the corn variety [inbred] are allowable . . . there can be no doubt that the specification provides and adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, page 25) that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred]. . . Accordingly, it is unclear to this merits panel what additional description is necessary.

Ex parte Carlson, p. 16. Here, Applicant has done just what the applicant in *Ex parte Carlson* did, that is claim hybrids having one parent that is a plant of an inbred variety. Further, Applicant reiterates that the specification contains an example of a hybrid produced by PH951 in the application as filed. *See* specification, pp. 57-58, Table 3. Thus, under *Ex parte Carlson*, "it is unclear . . . what additional description is necessary." *See Ex parte Carlson*, p. 16; *see also Regents of Univ. of Cal.*, 119 F.3d at 1569, 43 U.S.P.Q.2d at 1406 (stating that an Applicant is "not required to disclose every species encompassed by their claims even in an unpredictable art"). Additionally, claim 15, directed towards a plant having all the morphological and physiological traits of PH951 wherein PH951 was deposited with the ATCC, is only rejected on obviousness-type double patenting grounds, which, as described *infra*, has been obviated by filing a terminal disclaimer with this amendment.

Applicant reiterates that each member of the genus of hybrids which has PH951 has a parent and which is encompassed by claims 1-12, 17-21, 23, 25-28, 31-32 and 34-36 shares the identifying structural feature of the cells and/or chromosomes of inbred line PH951. An Applicant's claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others." *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (emphasis

added). One of skill in the art, utilizing technology well known in the art, could identify any member of the claimed genus.

The Examiner further states that the specification "does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement or set of chromosomes from PH951" and that "the claimed hybrids do not have the entire genomic characteristics of PH951, but only one set of chromosomes of PH951," and therefore the Examiner states that "even if one assumes that the SSR profile is a proper way to describe a hybrid, then it will require the SSR profiles of both parents to identify the hybrid not just the SSR profile of one of the parents." *See Office Action, p. 6.*

Applicant respectfully traverses this rejection. Most importantly, Applicant points out that the SSR profile of PH951 is sufficient to describe the claimed hybrids, and the Examiner's assertion that to describe the claimed hybrids using SSR requires "the SSR profiles of both parents" is improper. It is vital to conceptually understand that all F1 hybrid seed produced with PH951 will inherit the stable genetics of PH951. Therefore, knowing the SSR profile of PH951 permits the identification of any F1 hybrid produced with PH951 as one parent, as every such hybrid will have at least one set of PH951 chromosomes, and is therefore able to be identified using the SSR profile of PH951. Applicant has further described the SSR marker profile in Table 4 of the specification. *See specification, Table 4, pp. 61-64.* Given this information, one of ordinary skill in the art could identify any F1 hybrid with PH951 as a parent. Thus, Applicant respectfully submits the claimed invention is in accordance with the written description guidelines.

The Examiner states "where the breeding involves unknown various non-PH951 parents, all F1 hybrids will not receive the same set of chromosomes from each of the parents involved in the breeding." *See Office Action, p. 7.*

Applicant reiterates that each F1 hybrid which has PH951 as a parent and which is encompassed by claims 1-12, 17-21, 23, and 25-28 contain at least one set of chromosomes of inbred line PH951. Thus, these claims set forth "structural features commonly possessed by members of the genus that distinguish them from others," as only F1 hybrids with PH951 as a parent would have a complete set of PH951 chromosomes. *Regen. of Univ. of Cal.*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406. The claimed F1 hybrids are therefore described in such a way that

distinguishes them from other hybrids, which is sufficient to meet the written description requirement. *See id.*

Further, Applicant has not stated that all F1 hybrids made with PH951 would be phenotypically the same. It is true that genetics correlate with phenotype, and that the more highly related two individuals are genetically, the more similar their phenotype is likely to be. It is also true that if one desired to produce an F1 hybrid with the characteristics of the F1 hybrids disclosed in Table 1 and Table 3, one of skill in the art would prefer to utilize PH951 rather than spending the time and resources to develop a novel inbred. However, the written description requirement does not mandate a description by phenotype. At its foundation, the written description requirement serves an evidentiary function of making certain that the Applicant is in possession of a specific characteristic that identifies their claimed invention. The molecular marker data provided by Applicant in Table 4 serves this purpose. *See specification, Table 4, pp. 61-64.* The other inbred is not the point of patentability, nor is it what is being claimed. Rather, the relevant claims are drawn precisely to what is described, an F1 hybrid with the identifiable and unique molecular profile of PH951.

The Examiner states that new claims 13-14, 21, and 23 are rejected because "the SSR loci listed in Table 4 are not structurally described", and that "step (e) of claim 11 fails to describe the number of times steps (c) and (d) have to be repeated to produce backcross progeny plants with the desired trait and essentially all the morphological and physiological characteristics of the inbred." *See Office Action, p. 9.*

As an initial matter, it appears that the Examiner inadvertently referenced the incorrect claim number in the Office Action. The method claim containing the steps referred to is claim 13, not claim 11. Assuming this, Applicant respectfully traverses this rejection. Primers for the SSR markers listed in Table 4 are publicly available as stated in the present application.

Applicant respectfully directs the Examiner's attention to page 60, lines 19-23 of the specification where it states that "[p]rimers used for the SSRs reported herein are publicly available and may be found in the Maize GDB using the World Wide Web prefix followed by maizegdb.org (maintained by the USDA Agricultural Research Service), in Sharopova *et al.* (Plant Mol. Biol. 48(5-6):463-481), Lee *et al* (Plant Mol. Biol. 48(5-6); 453-461), or reported herein. Some marker information may be available from Paragen." A printout from the maize GDB website using bnlg1014 as an example has been included with this response as Appendix 3.

The printout shows the extent of amount of marker information available on the maize GDB, which includes primer sequences and map information. As explained in the specification, primer sequences for the public SSR markers listed in Table 4 can be easily obtained through the world wide web. *See* specification, p. 60, ll. 19-21 (describing the Maize GDB).

Further, Applicant asserts that the alleles of inbred line PH951 disclosed in the SSR profile of Table 4 is an identifying physical characteristic that describes the genus of minor variance of inbred line PH951. The SSR profile of PH951 is disclosed for numerous markers distributed throughout the genome as indicated by the Bin number of the marker, which denotes the marker location. A plant comprising 95% of the alleles of PH951 as disclosed in Table 4 would be produced, for example, by repeated backcrossing to PH951. A backcross conversion of PH951 as claimed in the instant application is described as comprising 95% of the alleles disclosed in Table 4. *See* specification, Table 4, pp. 61-64.

It is undisputed that fingerprinting with molecular markers is widely used for characterizing germplasm. Specifically, SSR profiles are known and can be practiced by one of ordinary skill in the art in maize breeding. One of ordinary skill has been enabled by the deposit to make and use minor variants of inbred corn line PH951, and one of ordinary skill in the art uses SSR markers to characterize backcross conversions of an inbred. Applicant has claimed in the manner used by those of ordinary skill in the art to characterize backcross conversions.

Regarding the failure of step (e) to describe the number of times steps (c) and (d) are repeated, Applicant refers to the response to Examiner's similar rejection under 35 U.S.C. § 112, second paragraph, *supra*. For similar reasons, step (e) of these claims is adequately described.

The Examiner states that new claims 25-27 are rejected because "the claims do not place any limitation on the traits conferred or affected by the single locus conversion," and that the claims "broadly encompass single loci that have not been discovered or isolated." *See* Office Action, p. 10. The Examiner also states that claims 28-30 are included in the rejection because the specification "provides no description of any plant produced by classical breeding methods such as backcrossing or recurrent selection," that no "individual genes conferring the desired traits have been characterized," and the relevant genes as claimed have not been isolated. *See* Office Action, p. 10.

Applicant respectfully traverses this rejection. The relevant claimed subject matter in claims 25-27 is the plant of claim 15 comprising a transgene or gene conversion. The

specification teaches multiple ways of introgressing or transforming a maize plant with various genes which confer advantageous traits desired in the plant. *See* specification, pp. 38-40. The specification also teaches many transgenes that could be inserted into the plant of claim 15. *See* specification, pp. 40-48. Applicant further notes that the claims are specifically drawn to a single gene conversion, and that phenotypes resulting from multigenic interactions are not the subject matter of these claims. For example, numerous exemplary transgenes for improved nutritional quality are taught on page 47 of the specification. There are many examples of single gene conversions which affect nutritional quality, see for example, as taught in the specification transforming a plant with an antisense gene of stearoyl-ACP desaturase to increase stearic acid content of the plant, *see* page 47, ll. 4-7, introduction of a phytase-encoding gene that would enhance breakdown of phytate, adding more free phosphate to the transformed plant, *see* page 47, ll. 9-12. In addition, *see* U.S. Patent No. 5,936,145, issued August 10, 1999, which is prior to the filing date of the instant application. Claim 39 reads as follows: "[t]he single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability." Thus, a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. One of skill in the art would recognize that it is common to transform a maize plant with various genes in order to confer desired traits to the maize plant.

The Examiner further states that claims 31-32 are included in the rejection "because the claims read on a method for crossing PH951 with a multitude of non-exemplified breeding partners which have not been characterized either morphologically or genetically." *See* Office Action, p. 10. Claims 34-36 are likewise rejected "because the claims require the use of a multitude of non-exemplified molecular markers." *See* Office Action, p. 11.

Applicant respectfully traverses this rejection. Claims 31-32 and 34-36 are directed towards methods for producing a maize plant derived from PH951 and developing a maize plant in a plant breeding program where the maize plant of claim 15 is used as a source of breeding material. The language of claims 31-32 and 34-36 makes clear that the maize plant of claim 15 must be used as breeding material in the breeding program described by claims 31-32 and 34-36.

Plant breeding techniques are well known to individuals skilled in the art. The specification describes many of these known techniques. *See* specification, p. 1, l. 18-p. 8, l. 2. In particular, the specification discusses the role of an inbred maize line in a plant breeding program:

Plant breeding techniques known in the art and used in a maize plant breeding program include, but are not limited to, recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, making double haploids, and transformation. Often a combination of these techniques are used. The development of maize hybrids in a maize plant breeding program requires, in general, the development of homozygous inbred lines, the crossing of these lines, and the evaluation of the crosses. Maize plant breeding programs combine the genetic backgrounds from two or more inbred lines or various other germplasm sources into breeding populations from which new inbred lines are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred lines and the hybrids from these crosses are evaluated to determine which of those have commercial potential.

Specification, p. 4, ll. 8-21.

As the specification makes clear, one of ordinary skill in the art would know how a maize inbred line is to be used in a plant breeding program. As taught by the specification, the maize inbred is used as a source of germplasm in creating new hybrid lines. It is thus clear from the specification, and to one of ordinary skill in the art, how PH951 would be employed in a plant breeding program.

One skilled in the art would thus recognize that Applicant was in possession of the invention described in claims 1-12, 17-21, 23, 25-28, 31-32 and 34-36 as of the filing date of the application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Double Patenting

The Examiner rejects claims 15-16 and 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 24 of U.S. Patent No. 6,774,290. The Examiner states that although the conflicting claims are identical, they are not patentably distinct from each other because the claims in both application and the patent are directed to maize plants having all the morphological and physiological characteristics of inbred maize line PH951 and parts of said plants. See Office Action, p. 11-12.

Applicant is herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c), which disclaims any term of a patent issuing from this application which would extend beyond the term of co-pending U.S. Patent No. 6,774,290. Therefore, Applicant submits that the

claims are in proper form for allowance and respectfully requests reconsideration and withdrawal of the obviousness-type double patenting rejection.

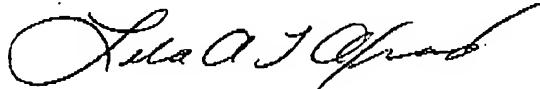
Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Please charge Deposit Account No. 26-0084 the amount of \$130.00 for the enclosed Terminal Disclaimer and \$120.00 for a one month extension of time from March 19, 2006 to April 19, 2006, under the provision of 37 C.F.R. § 1.136(a). No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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